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PATENT

Application No.: 10/698,025

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In the claims:

1. (Original) An aerosolization apparatus comprising:
a container containing a pharmaceutical formulation, the pharmaceutical formulation comprising an active agent and a propellant;
a metering chamber in communication with the container, the metering chamber adapted to hold a metered amount of the pharmaceutical formulation;
a valve to allow the metered amount of the pharmaceutical formulation to be released from the metering chamber when the valve is actuated; and
a pressurizer that applies pressure to the pharmaceutical formulation in the metering chamber while the pharmaceutical formulation is being released from the metering chamber,
wherein the metering chamber is sized so that at least 2 mg of the active agent is be aerosolized for delivery to a user during inhalation.
2. (Original) An aerosolization apparatus according to claim 1 wherein the pressurizer changes the volume of the metering chamber.
3. (Original) An aerosolization apparatus according to claim 1 wherein the pressurizer decreases the volume of the metering chamber.
4. (Original) An aerosolization apparatus according to claim 1 wherein the pressurizer changes the volume of the metering chamber and wherein the aerosolization apparatus further comprises a mechanism for returning the metering chamber to its original volume following actuation.
5. (Original) An aerosolization apparatus according to claim 1 wherein the metering chamber is sized so that at least 3 mg of the active agent is be aerosolized for delivery to a user during inhalation.
6. (Original) An aerosolization apparatus according to claim 1 wherein the metering chamber is sized so that at least 5 mg of the active agent is be aerosolized for delivery to a user during inhalation.

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7. (Original) An aerosolization apparatus according to claim 1 wherein the metering chamber is adapted to contain a volume of the pharmaceutical formulation of at least 50 μ l prior to actuation of the valve.

8. (Original) An aerosolization apparatus according to claim 1 wherein the metering chamber is adapted to contain a volume of the pharmaceutical formulation of at least 150 μ l prior to actuation of the valve.

9. (Original) An aerosolization apparatus according to claim 1 wherein the metering chamber is adapted to contain a volume of the pharmaceutical formulation of at least 300 μ l prior to actuation of the valve.

10. (Original) An aerosolization apparatus according to claim 1 wherein the pressurizer is arranged so that at least 50% of the aerosol particles generated have a diametric size of from 0.1 μ m to 10 μ m.

11. (Original) An aerosolization apparatus according to claim 1 wherein the pressurizer is arranged so that at least 80% of the aerosol particles generated have a diametric size of from 0.1 μ m to 10 μ m.

12. (Original) An aerosolization apparatus according to claim 1 wherein the pressurizer comprises a plunger that is capable of changing the volume of the metering chamber.

13. (Original) An aerosolization apparatus according to claim 1 wherein the pressurizer comprises a plunger that is capable of changing the volume of the metering chamber, wherein the plunger is adapted to be pressurized by the pressure of the pharmaceutical formulation within the container.

14. (Withdrawn) An aerosolization apparatus according to claim 1 wherein the pressurizer comprises a flexible wall of the metering chamber.

15. (Withdrawn) An aerosolization apparatus according to claim 1 wherein the pressurizer comprises a flexible wall of the metering chamber, wherein the flexible wall is adapted to be pressurized by the pressure of the pharmaceutical formulation within the container.

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16. (Original) An aerosolization apparatus according to claim 1 wherein the pressurizer comprises a source of pressurized gas.

17. (Original) An aerosolization apparatus according to claim 1 wherein the pressurizer comprises a source of pressurized gas, wherein the source of pressurized gas is within the container.

18. (Withdrawn) An aerosolization apparatus according to claim 1 wherein the pressurizer comprises a bi-stable member movable between a first position and a second position and wherein the pressure within the metering chamber is increased when the bi-stable member moves to the second position.

19. (Withdrawn) An aerosolization apparatus according to claim 18 wherein the bi-stable member comprises a bi-stable dome.

20. (Withdrawn) An aerosolization apparatus according to claim 18 wherein the bi-stable member comprises an interior surface in communication with the metering chamber and an exterior surface in communication with the interior of the container.

21. (Original) An aerosolization apparatus comprising:
a container containing a pharmaceutical formulation, the pharmaceutical formulation comprising an active agent and a propellant;
a metering chamber in communication with the container, the metering chamber having a metering volume of at least 150 μ l and being adapted to hold a metered amount of the pharmaceutical formulation;
a valve to allow the metered amount of the pharmaceutical formulation to be released from the metering chamber when the valve is actuated; and
a pressurizer that applies pressure to the pharmaceutical formulation in the metering chamber while the pharmaceutical formulation is being released from the metering chamber.

22. (Original) An aerosolization apparatus according to claim 21 wherein the pressurizer changes the volume of the metering chamber.

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23. (Original) An aerosolization apparatus according to claim 21 wherein the pressurizer changes the volume of the metering chamber and wherein the aerosolization apparatus further comprises a mechanism for returning the metering chamber to its original volume following actuation.

24. (Original) An aerosolization apparatus according to claim 21 wherein the pressurizer is arranged so that at least 50% of the aerosol particles generated have a diametric size of from 0.1 μm to 10 μm .

25. (Original) An aerosolization apparatus according to claim 21 wherein the pressurizer comprises a plunger that is capable of changing the volume of the metering chamber, wherein the plunger is adapted to be pressurized by the pressure of the pharmaceutical formulation within the container.

26. (Withdrawn) An aerosolization apparatus according to claim 21 wherein the pressurizer comprises a flexible wall of the metering chamber, wherein the flexible wall is adapted to be pressurized by the pressure of the pharmaceutical formulation within the container.

27. (Original) An aerosolization apparatus according to claim 21 wherein the pressurizer comprises a source of pressurized gas, wherein the source of pressurized gas is within the container.

28. (Withdrawn) An aerosolization apparatus according to claim 21 wherein the pressurizer comprises a bi-stable member movable between a first position and a second position and wherein the pressure within the metering chamber is increased when the bi-stable member moves to the second position.

29. (Original) An aerosolization apparatus comprising:
a container containing a pharmaceutical formulation, the pharmaceutical formulation comprising insulin and a propellant;
a metering chamber in communication with the container, the metering chamber adapted to hold a metered amount of the pharmaceutical formulation;

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a valve to allow the metered amount of the pharmaceutical formulation to be released from the container when the valve is actuated; and

a pressurizer that applies pressure to the pharmaceutical formulation in the metering chamber while the pharmaceutical formulation is released from the metering chamber.

30. (Original) An aerosolization apparatus according to claim 29 wherein the pressurizer comprises a plunger that is capable of changing the volume of the metering chamber, wherein the plunger is adapted to be pressurized by the pressure of the pharmaceutical formulation within the container.

31. (Withdrawn) An aerosolization apparatus according to claim 29 herein the pressurizer comprises a bi-stable member movable between a first position and a second position and wherein the pressure within the metering chamber is increased when the bi-stable member moves to the second position.

32. (Original) A method of aerosolizing a pharmaceutical formulation, the method comprising:

containing a pharmaceutical formulation in a container, the pharmaceutical formulation comprising an active agent and a propellant;

metering an amount of the pharmaceutical formulation in a metering chamber in communication with the container;

releasing the pharmaceutical formulation from the metering chamber when a valve is actuated; and

applying pressure within the metering chamber during the release of the pharmaceutical formulation,

wherein at least 2 mg of the active agent is be aerosolized for delivery to a user during inhalation.

33. (Original) A method according to claim 32 wherein the pressure is added to the metering chamber by decreasing the volume of the metering chamber.

34. (Original) A method according to claim 32 wherein at least 3 mg of the active agent is aerosolized for delivery to a user during inhalation.

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35. (Original) A method according to claim 32 wherein at least 5 mg of the active agent is aerosolized for delivery to a user during inhalation.

36. (Original) A method according to claim 32 wherein at least 50% of the aerosol particles generated have a diametric size of from 0.1 μm to 10 μm .

37. (Original) A method according to claim 32 wherein at least 80% of the aerosol particles generated have a diametric size of from 0.1 μm to 10 μm .

38. (Original) A method according to claim 32 wherein the pressure is applied by a plunger.

39. (Original) A method according to claim 32 wherein the pressure is applied by a plunger, wherein the plunger is adapted to be pressurized by the pressure of the pharmaceutical formulation within the container.

40. (Withdrawn) A method according to claim 32 wherein the pressure is applied by a flexible wall of the metering chamber, wherein the flexible wall is pressurized by the pressure of the pharmaceutical formulation within the container.

41. (Original) A method according to claim 32 wherein the pressure is applied from a source of pressurized gas.

42. (Withdrawn) A method according to claim 32 wherein the pressure is applied by a bi-stable member movable between a first position and a second position and wherein the pressure within the metering chamber is increased when the bi-stable member moves to the second position.

43. (Original) A method of aerosolizing an insulin formulation, the method comprising:

- containing a pharmaceutical formulation in a container, the pharmaceutical formulation comprising insulin and a propellant;
- metering an amount of the pharmaceutical formulation in a metering chamber in communication with the container;

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releasing the pharmaceutical formulation from the metering chamber when a valve is actuated; and

applying pressure within the metering chamber during the release of the pharmaceutical formulation.

44. (Original) A method according to claim 43 wherein at least 2 mg of insulin is aerosolized for delivery to a user.

45. (Original) A method according to claim 43 wherein at least 3 mg of insulin is aerosolized for delivery to a user.

46. (Original) A method according to claim 43 wherein at least 5 mg of insulin is aerosolized for delivery to a user.

47. (Original) A method according to claim 43 wherein the pressure is applied by a plunger, wherein the plunger is adapted to be pressurized by the pressure of the pharmaceutical formulation within the container.

48. (Withdrawn) A method according to claim 43 wherein the pressure is applied by a flexible wall of the metering chamber, wherein the flexible wall is pressurized by the pressure of the pharmaceutical formulation within the container.

49. (Original) A method according to claim 43 wherein the pressure is applied from a source of pressurized gas.

50. (Withdrawn) A method according to claim 43 wherein the pressure is applied by a bi-stable member movable between a first position and a second position and wherein the pressure within the metering chamber is increased when the bi-stable member moves to the second position.